

DOH Feedback related to TAC Suggestions

Operational Process Improvement

Suggestions highlighting or emphasizing important aspects of current process:

- Maintain the current process flow of staff screening followed by public comment process and then final decision by Secretary of the Department of Health, or designee. (A-4 and B-5)
- Continue to obtain quality, access, and utilization data, as well as licensure information from other state agencies as it relates to CON applications/applicants. (B-4)
- Retain the current service area definition methodology for use in CON process. (B-6)
- Maintain the mechanism for notifying the public of Letter of Intent and receipt of application, which may trigger submission of competing applications. (D-1)
- Continue to batch competing applications for similar service types and geographic areas into the same concurrent review cycles. (D-4)

Department of Health comments:

Based in part on recommendations in the JLARC performance audit, the Department is examining ways to improve its current process.

Suggestions based upon observations similar to those cited in JLARC report:

- Assure the availability of sufficient resources (including staff with technical expertise). (B-3)
- Provide a timely, accountable and reasonable process in compliance with existing statute/rule. (D-7)
- Assure consistency of review with reliability among analysts. (E-5)

Department of Health comments:

The Department supports those goals.

New Suggestions:

- Change the current process flow of staff screening followed by public comment process and then final decision by Secretary of the Department of Health, or designee to: staff preliminary analysis followed by public comment process and final decision by Secretary of Department of Health, or designee. This change would permit written response and public hearing formats to further support public interaction between applicant and decision-maker (A-4, B-5, and E-2)

Suggestions from Technical Advisory Committee

- Provide Request-for-Proposal invitations for CON proposals based on service needs determined in the State Health Plan. (D-2)
- Use CON program plan-driven review cycles which specify certain decision dates and review periods, such as 90-day cycles with decision dates on the 15th of each quarter rather than provider-driven receipt-of-application individual cycles. (D-3)
- Develop additional criteria and standards to address differential factors among competing applications for a defined need that would not support approval of all applications. (D-4, E-4, and F-2)
- Consider the use of expedited abbreviated cycles for applications which comply with the state health plan and have minimal impact on area health services. (D-5)
- Assure that the burden-of-proof is on the applicant to provide documentation of community need and detailed responsiveness to CON criteria and standards. (E-3)
- Explore the potential for negotiation prior to final decision in order to adjust project size, cost and scope to accommodate demonstrated needs (needs to occur prior to ex parte or need to reopen for public comment phase) in lieu of denial/reapplication process. (E-4)
- Utilize planning-based, analytically-oriented, evidence-based health care criteria and standards which are updated at least biennially. (F-1)
- Develop a process for supporting participation in clinical trials of a duly constituted institutional review board of an accredited school of medicine or other health profession designed to assure the safe, appropriate, and cost-effective transfer of new medical technology or services throughout the state. The participation should not alter the bed complement, facility approval, or service approval currently held by the organization seeking approval for participation. (F-5)
- To address the consumer's desire for quality health service by all providers, assure that CON regulation applies to all similar services within a specific category irrespective of owner or type of reimbursement. (F-6)

Department of Health comments:

Issuing a staff analysis, which states the rationale for a decision on an application, prior to the public comment process would deprive the program of very valuable public comments, many of which are incorporated into the final analysis. It is difficult to see what value the release of a partial draft analysis that is uninformed by public comment would have for creating a better, more transparent process. It would likely give the

Suggestions from Technical Advisory Committee

impression that the program had committed to a course of action without public input, creating a less trusted process. It may also lead the applicant to modify the application, requiring even more analysis by staff and the public.

One suggestion states that “in lieu of denial” of an application, the program should engage in negotiation with the applicant until the project satisfies the identified community need. Fairness and efficiency require that the program use an open process to decide the application that was submitted, not one the applicant later decides it should have submitted. It is difficult to see how the program could negotiate with the applicant when many other interested parties, and the public, may have an interest and be participating in the process. Such a process would not appear transparent to all the parties who are not part of the negotiations. Moreover, in a concurrent review process, with more than one applicant competing, it is not clear how such negotiations could even be structured.

It is not clear what the recommendation about clinical trials is requesting. Thousands of clinical trials take place in the state each year with no involvement in the CON process, unless the trial were to take place in a manner or in a place that requires a CON (for example, building a new neonatal ICU or organ transplant unit in order to conduct the trial.) The recommendation further provides that “The participation should not alter the bed complement, facility approval, or service approval currently held by the organization seeking approval for participation” If that were the case, then the facility would not even need a CON. Nor is “transfer of new medical technology or service” currently subject to CON review.

Suggestions from Technical Advisory Committee

Transparency

Suggestions based upon observations similar to those cited in JLARC report:

- Use electronic applications, processing and reporting for public transparency, accountability and public input; (E-1)
- Provide transparency during all phases of the CON process (pre-analysis by staff, post-analysis by staff, pre-public comment, and post-public comment) of data related to:
 - volumes,
 - application types,
 - appeals/resolutions,
 - denials,
 - compliance, and
 - other related application data and information. (E-6)
- Provide for public disclosure of analysis, including all data and data sources used to reach analysis, prior to close of public comment; (B-2)

Department of Health comments:

The Department supports a transparent process open to participation by interested parties and the public. The recommendation about the use of electronic materials is similar to two recommendations made in the JLARC performance audit regarding the availability of CON material on the website, and electronic tracking of application reviews. The Department concurred with the two recommendations. The CON website has already been significantly updated, and work continues. A new work load tracking and analysis tool is also being created.

Information submitted during an application process is made available to other parties participating. Given that process, it is difficult to see how disclosure of a draft analysis, prior to public comment being concluded, makes the process more transparent. It does seem calculated to allow the applicant to submit more or different information in order to avoid denial. A process that focuses primarily on the interests of the applicant in avoiding denial is not a more transparent process.